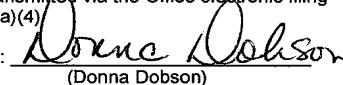


Reply Brief

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Dated: 05/28/2010

Signature:


(Donna Dobson)

Docket No.: 74688/P004CP1D1/10804933

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Raymond P. Feith et al.

Application No.: 10/816,183

Confirmation No.: 7854

Filed: March 31, 2004

Art Unit: 3763

For: MULTI-VALVE INJECTION/ASPIRATION
MANIFOLD WITH NEEDLELESS ACCESS
CONNECTION

Examiner: Q. H. Vu

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

As required under 37 C.F.R. § 41.41(a)(1), this Reply Brief is filed within two (2) months of the Examiner's Answer dated March 30, 2010, and is in furtherance of the Appeal Brief filed on February 22, 2010.

No fee is required for this REPLY BRIEF.

This brief contains items under the following headings pursuant to M.P.E.P. § 1208:

- I. Status of Claims
- II. Grounds of Rejection to be Reviewed on Appeal
- III. Argument
- IV. Conclusion

I. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 7 claims pending in application.

B. Current Status of Claims

1. Claims canceled: 4-6, 9-19 and 22-23
2. Claims withdrawn from consideration but not canceled: 7-8 and 20-21
3. Claims pending: 1-3, 7-8, and 20-21
4. Claims allowed: None
5. Claims rejected: 1-3

C. Claims On Appeal

The claims on appeal are claims 1-3.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. First Ground of Rejection – Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
- B. Second Ground of Rejection – Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by US 4,946,448 (hereinafter *Richmond*).
- C. Third Ground of Rejection – Claims 1-3 are rejected under 35 U.S.C. § 103(a) as unpatentable over US 4,922,954 (hereinafter *Blomquist*) in view of US 3,889,710 (hereinafter *Brost*).
- D. Fourth Ground of Rejection – Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, and 5-7 of US 6,364,861 (hereinafter the ‘861 patent).

III. ARGUMENT

This Reply Brief addresses specific assertions and issues raised by the Examiner's Answer of March 30, 2010. Thus, for the sake of brevity, the arguments in this Reply Brief do not repeat the arguments presented in the Appeal Brief of February 22, 2010. Appellant relies upon its arguments in the Appeal Brief for any argument in the Examiner's Answer not specifically addressed below.

A. First Ground of Rejection

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In the Response to Argument section, Appellee states that the Appellant is using non-elected species of Figures 10-13 to support its argument for elected species of Figures 14-16. Examiner's Answer at 6. However, Appellant may properly rely upon Figures 11-13 in traversing the rejection because the Restriction Requirement of January 24, 2008 did not restrict these embodiments. *See generally* Restriction Requirement. Further, Appellee provides two reasons for the § 112 rejection.

First, Appellee argues that the Specification does not mention pressure resulting from fluid in the flow channel. Examiner's Answer at 6. On the contrary, fluid in a flow channel is described in the Specification at Figure 11. Application at 11, Figure 11. The position of the valve element 70, 74 is the same in Figures 11, 12, and 14. Thus, one of ordinary skill in the art would recognize that behavior of the valve when fluid is in the flow channel, as depicted specifically in Figure 11, would be similarly applicable to Figures 12 and 14. In other words, fluid in the flow channel creates a first pressure in Figures 11, 12, and 14.

Second, Appellee argues that the Specification does not mention a third pressure greater than one of said first pressure and said second pressure. Examiner's Answer at 6. As noted above, Figure 14 depicts the position of the valve element 74 under normal fluid flow conditions, and thus, at a first pressure. When suction is applied to perform aspiration, as depicted in Figure 16, valve element 74 raises off shoulder 103. Application at 13, Figure 16. One of ordinary skill in the art would recognize that to facilitate movement of the valve element 74, this suction, or third pressure (Figure 16), would have to be greater than a first pressure from normal fluid flow (Figure 14). Otherwise, the valve element 74 would not move to permit the aspiration. In other words, the Specification does describe a third

pressure greater than one of said first pressure or said second pressure. As the claim limitations used by the Appellee in supporting the § 112 rejection are supported by the written description for the reasons set forth above, Appellant respectfully requests that the § 112 rejection be reversed.

B. Second Ground of Rejection

Claim 1 is rejected under 35 U.S.C. § 102(b) as anticipated by *Richmond*. Claim 1 requires a valve element forming a second seal with a second valve seat. In the Response to Arguments section, Appellee argues that *Richmond* teaches these limitations when valve disc 84 rests on Projections 82 in the dashed line position of Figure 2. *See* Examiner's Answer at 7. The Examiner's Answer indicates a misunderstanding of the meaning of seat and seal. Appellant does not believe that Projections 82 form a valve seat, but rather merely a valve support. *See* Appeal Brief at 7. Even assuming, *arguendo*, that the Projections could be construed as forming a valve seat, *Richmond* still fails to teach forming a valve seal with the alleged valve seat. In *Richmond*, when a pressure is applied from fluid in the flow channel, the check valve opens. *Richmond* at col. 4, lines 45-62. Projections 82 support the valve disc 84 while fluid flows past the valve disc 84 and around the Projections 82. *Id.* One of ordinary skill in the art would understand the function of a seal to be inhibiting fluid flow at the seal. In contrast, *Richmond* describes permitting fluid flow at the alleged "seal." This contradiction is not resolved by the Examiner's Answer. Because *Richmond* fails to teach all limitations of claim 1, for at least the reasons set forth above, Appellant respectfully requests that the reversal of the § 102(b) rejection.

C. Third Ground of Rejection

1. Lack of All Limitations

Claims 1-3 are rejected under 35 U.S.C. § 103(a) as unpatentable over *Blomquist* in view of *Brost*. Appellant's claim 1 requires forming a first seal with the first valve seat in response to a first pressure, the first pressure resulting from fluid in the flow channel. The Examiner's Answer states that Specification does not describe on pages 13-14 that a first seal is formed with the first valve seat in response to a first pressure. *See* Examiner's Answer at 8. Particularly, the Examiner's Answer repeats that the Specification does not mention any pressure with respect to Figure 14. *Id.* On the contrary, a pressure from a fluid in the flow

channel is depicted in the Specification at Figure 11. Application at 11, Figure 11. The position of the valve element 70, 74 is the same in Figures 11, 12, and 14. Thus, one of ordinary skill in the art would recognize that behavior of the valve when fluid is in the flow channel, as depicted specifically in Figure 11, would be similarly applicable to Figures 12 and 14. In other words, at normal state, fluid in the flow channel creates a first pressure in Figures 11, 12, and 14.

Further, as shown in Figure 12, this first pressure from fluid in the flow channel creates a first seal between valve element 70 and valve seat 96. Application at 12. Similarly, as shown in Figure 14, this first pressure from fluid in the flow channel creates a first seal between valve element 74 and valve seat 110. Application at 13. In contrast, *Blomquist* forms a first seal between valve element 37 and valve seats 38 and 39 at equilibrium, that is, when there is no flow through the valve and no pressure differential. *See Blomquist* at col. 5, lines 17-35; Appeal Brief at 8-9; Examiner's Answer at 8. Thus, *Blomquist* does not teach forming a first seal in response to a first pressure from fluid in the flow channel. Further, *Brost* is not relied upon as teaching this limitation. Thus, neither *Blomquist* nor *Brost*, alone or in combination, describe every limitation of claim 1. As such, Appellant respectfully requests reversal of the § 102(b) rejection of claim 1.

2. Lack of a Rational Reason to Combine

Further, in the Appeal Brief, the Appellant showed that one of ordinary skill in the art at the time of the invention would have no rational reason to combine *Blomquist* and *Brost*. Appeal Brief at 9. *Brost* is a check valve assembly intended to allow fluid flow in only one direction. *See Brost* at col. 3, line 63 to col. 4, line 13. In contrast, *Blomquist* is a vent assembly intended to freely permit gas flow in two directions to equalize pressure on both sides of the vent. *See Blomquist* at col. 1, line 64 to col. 2, line 2. Thus, combining the two references would render one or the other reference unsuitable for its intended purpose. Appeal Brief at 9-10. Appellee responded in two ways.

First, Appellee argues that one of ordinary skill in the art would combine the *Blomquist* device with an injection lumen taught in *Brost* to provide fluid communication with the other device. Examiner's Answer at 10. It is well settled that if a "proposed modification would render the prior art invention being modified unsatisfactory for its

intended purpose, then there is no suggestion or motivation to make the proposed modification.” M.P.E.P. § 2143.01(V) (citing *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)). The rationale provided by Appellee is improper—as described above, combining the two references would defeat the object of *Brost*.

Second, Appellee argues that one of ordinary skill in the art would combine the *Blomquist* device with the check valve 13 of *Brost* to create a valve system like the valve of the claimed invention. Examiner’s Answer at 10. Appellee is relying on Appellants’ own disclosure as a road map for selecting and combining elements from the cited references. The use of such hindsight is not appropriate to establish a motivation to combine. *See* M.P.E.P. § 2145(X)(A); *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1742 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”). Thus, for the reasons set forth above, Appellant respectfully requests reversal of the § 102(b) rejection of claim 1.

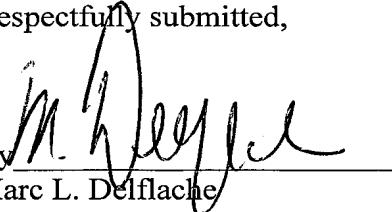
D. Fourth Ground of Rejection

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, and 5-7 of the ‘861 patent. Applicant relies on the arguments presented in the Appeal Brief. *See* Appeal Brief at 10.

Appellant believes no fee is due with this response. Please charge any fees required or credit any overpayment to Deposit Account No. 06-2380, under Order No. 74688/P004CP1D1/10804933 during the pendency of this Application pursuant to 37 C.F.R. §§ 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

Dated: May 28, 2010

Respectfully submitted,

By 

Marc L. Delflache

Registration No.: 28,942
FULBRIGHT & JAWORSKI L.L.P.
2200 Ross Avenue, Suite 2800
Dallas, Texas 75201-2784
(214) 855-7150
(214) 855-8200 (Fax)
Attorney for Applicant